REMARKS/ARGUMENTS

Favorable reconsideration of this application, as presently amended, is respectfully requested.

Claims 22-23 have been cancelled and the subject matter thereof has been introduced into Claim 20.

According to a feature of the invention, a disposable container allows operation under sterile conditions in any environment devoid of sterile hoods and which may be obtained by assembling already known constructional elements in a simple and low-cost manner. To this end, it includes a top end comprising a removable lid including a first opening passed through by a first cannula that can be connected operationally to the external environment to control entry and exit of air in conjunction with transfer of a fluid biological material into or from the container, a second opening passed through by a second cannula that can be accessed by a hollow needle to transfer a fluid biological material into or from the container through the hollow needle, and a third opening passed through by a third cannula operationally connected to an attachment configured to receive and accommodate one end of a syringe to transfer a fluid biological material into or from the container through the third cannula whose length is at least equal to the height of the container.

The top end of the first cannula includes a removable stopper for controlling the entry and exit of air in conjunction with the transfer of a fluid biological material into or from the container, and a tap is arranged between the top end and the first cannula, and wherein the second cannula can be accessed by the hollow needle through pierceable membrane. For example, with reference to the non-limiting embodiment, the top end 5 of the first cannula 4 of the container 1 includes a removable stopper 20 and a tap 6 is arranged between the top end 5 and the first cannula 5, and wherein the second cannula 8 can be accessed by the hollow needle 9 through pierceable membrane 10.

Claims 20-23 were rejected under 35 U.S.C. § 103 as being obvious over U.S. patent publication 2002/0185457 (Smith et al) in view of U.S. patent 5,663,051 (Vlasselaer). According to this rejection, Vlasselaer teaches a piercable membrane in the form of a sterile septum. This rejection is respectfully traversed.

According to the Office Action, Smith et al teaches a centrifuge tube comprising an open top end and a closed bottom end, wherein the top end comprises a removable lid including a first opening (42), a second opening (34) passed through by a second cannula (38) that can be accessed by a hypodermic needle, and a third opening (32) passed through by a third cannula (36) operationally connected to a port.

The Office Action recognizes that Smith et al is silent about the first opening (42) being passed through by a first cannula that can be connected to the external environment to control entry/exit of air in conjunction with transfer of a biological material into or from the container, but considers that Vlasselaer teaches (reference is made to Fig. 6) that the tube contains the air vent entry port (82) to facilitate fluid flow into centrifuge tube (76). Air filter (84) is attached to entry port (82) to prevent contamination and the vent air filter (84) is covered with a cap (86).

According to the Office Action, it is desirable to provide a filter and a cap to avoid contamination through the vent (i.e. the air vent entry port 82). Moreover, according to the Office Action, it would have been obvious to one ordinary skilled in the art to combine the air filter and cap of Vlasselaer in the vent hole (42) of the centrifuge tube of Smith et al in order to avoid contamination to the sample being centrifuged. It is nonetheless submitted that the amended claims define over this prior art.

The Office Action indicates that Vlasselaer (reference is made to Fig. 6) comprises an air vent entry port (82) with an air filter (84), to prevent contamination. On the contrary, the present invention does not provide or claim an air filter that avoids contamination. Only

according to a preferred embodiment of the present invention (see pg. 3, lines 17-19), the first cannula can be operationally connected to means, such as filtering means, which ensure the sterility of the air entering into said container.

In Vlasselaer, the air filter (84) is attached to entry port (82) to prevent contamination. On the contrary, in the present invention (see pg. 5, lines 26-30), the first hole (3) houses the first cannula (4), which is operationally connected to a seat (5); a tap (6) is arranged between said seat (5) and said first cannula (4). This tap (6) can be in an opened or closed position. The tap (6) is opened when the material is transferred into/out the container, so as to allow the exit of a volume of air to compensate the entry of a volume of material from the container or to allow the entry of a volume of air to compensate the exit of a volume of material in the container (see pg. 7, lines 28-30 and pg. 8, lines 22-25). The tap (6) is closed when the container is subjected to centrifugation, so that it is no longer necessary to use the removable lid (20).

The disposable container for centrifuging according to the present invention does not comprise an air filter, which avoids contamination, in any part of the container and even in tap (6).

Accordingly, following the teaching of Vlasselaer, the person skilled in the art would have added an air filter to the vent port of Smith et al, but not the tap (6) according to the present invention, as the tap (6) is not described in Vlasselaer.

Regarding claim 22 (now part of claim 20), the Office Action indicates that Smith et al and Vlasselaer teach that the centrifuge tube further comprising a tube ("tap") entering into the air vent entry port (82) and that "tap" is sufficiently broad to read on the structure that is inserted into an entry port. This is respectfully traversed.

Smith et al does not teach anything about a "tap" or a tube entering in the air vent port. Vlasselaer does not teach that the centrifuge tube (76) further comprises a tube entering

into the air vent entry port (82). Vlasselaer teaches that tubing (74) is attached to tube (76) through entry port (78), adapted with fitting (80), which may be any type of locking lip adapted for sterile connection or a sterile septum adapted for connection with sterile fluid bags and tubes (col. 11, lines 21-33).

The "tap" according to the present invention is different from the "tube" according to Vlasselaer and the two terms cannot be misunderstood or mistaken.

Regarding claims 23 (now also part of claim 20), 24, 26 and 27, the Office Action states that Smith et al teaches that the second cannula can be accessed by a hypodermic needle but is silent about being accessed through a pierceable membrane.

According to the Office Action, Vlasselaer teaches that the fitting 80 can be a sterile septum. The Office Action concludes that it is desirable to provide a sterile septum to create a sealable membrane to transfer samples without contamination. Moreover, the Office Action considers states that it would be obvious to one ordinary skilled in the art to combine the sterile septum of Vlasselaer to the second cannula of Smith et al in order to provide a sterile entry port for the hypodermic needle. Nonetheless, the amended claims define over this interpretation.

First, the membrane (10) used in the present invention is a pierceable membrane and not a sealable membrane. Moreover, according to Vlasselaer, fitting (80) may be a sterile septum adapted for connection with sterile fluid bags and tubes (see col. 11, lines 25-26), i.e. a septum with large pores so as to allow the cells of the blood to pass from the sterile connecting tube (74) into the centrifuge tube (76).

Hence, the fitting (80) according to Vlasselaer is very different from the pierceable membrane (10) according to the present invention. A hollow needle is able to pierce this membrane (10) and penetrate into the container (1) (see pg. 6, lines 3-4), and the pierceable membrane closes again by itself, when the needle is removed.

Accordingly, following the teaching of Vlasselaer, the person skilled in the art would have added the porous septum of Vlasselaer to the second cannula of Smith et al but not a pierceable membrane to be pierced by a needle, as the pierceable membrane is not described in Vlasselaer.

Applicant therefore believes that the present application is in a condition for allowance and respectfully solicits an early notice of allowability.

Respectfully submitted,

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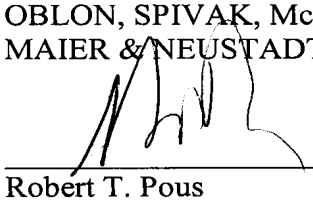

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